

COLLORA<sub>LLP</sub>

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June 21, 2013

VIA ELECTRONIC DELIVERY AND U.S. MAIL

Ms. Susan Liner  
Recall Coordinator  
U. S. Food and Drug Administration  
One Montvale Avenue  
Stoneham, MA 02180

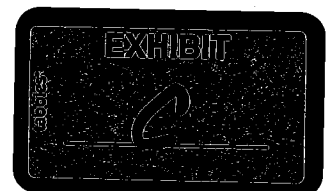
Mr. Mark Rubbins  
Division Group Supervisor  
J.F.K. Federal Building  
15 New Sudbury Street  
Room E-400  
Boston, MA 02203

Re: Ameridose: Return and disposal of expired products

Dear Ms. Liner and Mr. Rubbins:

As the product recall conducted by Ameridose is nearing completion, we would like to propose a process for returning and disposing of the expired products being held by Ameridose. An inventory of these products is attached and has been broken into three categories:

- (1) Expired Bulk Products: Ameridose proposes to return these products to vendors for monetary credit. Many vendors have expired vials programs that will issue credit for expired products that are sealed in original containers if they are return within a specific date range (usually within six months of expiration). Expired bulk products that are not accepted by a vendor will be sent to a waste disposal company and the controlled substances will be sent to a licensed controlled substance reverse distributor as waste.
- (2) Expired Finished Goods: This category includes both finished products and stock solutions. Ameridose proposes to send these goods to a waste disposal company and the controlled substances will be sent to a licensed controlled substance reverse distributor as waste. Please note that this category includes expired in-process stock solutions and expired finished goods that the DEA and/or FDA sampled.



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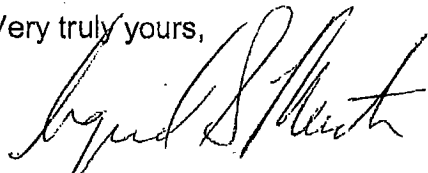
- (3) Expired Recalled Waste: Like expired finished goods, Ameridose proposes to send these products to a waste disposal company and the controlled substances will be sent to a licensed controlled substance reverse distributor as waste.

Ameridose is seeking to return and dispose these products for a number of reasons. First, Ameridose will suffer substantial financial harm if it misses the opportunity to return expired bulk products within the time frame set by the vendor. Second, the large quantity of narcotics that are now at Ameridose pose risks that Ameridose would like to eliminate. Although Ameridose has a good security system in place, the sheer quantity of narcotics that have been accumulated through the recall process is a concern. It would be best to eliminate any possibility of theft by returning or destroying these controlled substances. Third, to ensure the continued security of Class II substances, Ameridose is conducting a weekly inventory count. Given the amount of product on-hand, this is a costly endeavor. Finally, Ameridose would like to clear out space and have the ability to make whatever changes regulators will recommend for reopening the facility.

Please contact me and let me know whether the plan proposed above is acceptable.

Thank you for your attention to this matter.

Very truly yours,



Ingrid S. Martin

cc: Nancy Dolberg, Massachusetts Department of Public Health (electronic delivery only)  
Nathaniel Yaeger, Chief of Health Care Fraud Unit, United States Attorney's Office (electronic delivery only)